UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

DEC 10 2007

Stephen Baxter
Oblon, Spivak, McClelland, Maier & Neustadt, PC
1940 Duke Street
Alexandria VA 22314

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,107,458

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 6,107,458, which claims the human drug product Mycamine® (micafungin sodium), a pharmaceutical composition comprising Mycamine® (micafungin sodium) and a method of using Mycamine® (micafungin sodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,265 days

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent Nos. 5,376,634 and 6,265,536 based on the regulatory review period of NDA No. 21-506 for the human drug product, Mycamine® (micafungin sodium).

Applicant also has sought extension under 35 U.S.C. § 156(d)(1) for U.S. Patent Nos. 5,376,634, 6,107,458 and 6,265,536 for NDA 21-754. Notices of Final Determination will be sent under separate cover for each patent for NDA 21-754. 35 U.S.C. § 156(a)(2) states that, "the term of the patent has never been extended under subsection(e)(1) of this section." Therefore, Applicant cannot extend the same patent for the approvals of NDA 21-506 and NDA 21-754. Accordingly, two patents are eligible for extension based on the regulatory review periods for Mycamine® (micafungin sodium) in NDA 21-506 and 21-754.

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the applications for patent term extension for the above-identified patent and U.S. Patent No. 6,265,536 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted. (Absent an express election, a certificate of extension will be issued in U.S. Patent No. 5,376,634.) In the absence of a request for reconsideration, and if U.S. Patent No. 6,107,458 is elected, the Commissioner will issue to the applicant a certificate of extension, under seal, for a period of 1,265 days in U.S. Patent No. 6,107,458.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of September 26, 2006, (71 Fed. Reg. 56157), would be 1,360 days. Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (1,493 days - 878 days) + 1,053 days
	=	1,360 days (3.7 years)

Since the regulatory review period began March 29, 1998, before the patent issued (August 22, 2000), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From March 29, 1998, to and including, August 22, 2000, is 878 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,360 days, would extend the patent from September 29, 2015, to June 20, 2019, which is beyond the 14-year limit (the approval date is March 16, 2005, thus, the 14 year limit is March 16, 2019). The period of extension is thus limited to 1,265 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, September 29, 2015, to and including, March 16, 2019, or 1,265 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,107,458
Granted:	August 22, 2000
Original Expiration Date[1]:	September 29, 2015
Applicant:	Hidenor Ohki, et al.

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Owner of Record:	Fujisawa Pharmaceutical Co., Ltd.
Title:	Polypeptide Compound and a Process for Preparation Thereof
Product Trade Name:	Mycamine® (micafungin sodium)
Term Extended:	1,265 days
Expiration Date of Extension:	March 16, 2019

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: Mycamine® (micafungin sodium)
FDA Docket No.: 2006E-0023

DATE 12-10-07 APPLICATION NUMBER 08/809723

DOC CODE TERM. PTO-ELC DOC DATE 12-10-07

DELIVER THE ATTACHED FIFLE/DOCUMENT TO THE TC SCANNING CENTER

CONTRACTOR: THE ATTACHED FILE/DOCUMENT MUST BE INDEXED AND SCANNED INTO IFW WITHIN **8** WORK HOURS; UPLOADING OF THE SCANNED IMAGES SHOULD OCCUR NO LATER THAN **16** WORK HOURS FOLLOWING RECEIPT OF THIS REQUEST

AFTER SCANNING, ORIGINAL DOCUMENTS SHOULD BE BOXED IN ACCORDANCE WITH INSTRUCTIONS

UNITED STATES PATENT AND TRADEMARK OFFICE

DEC 10 2007

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Stephen Baxter
Oblon, Spivak, McClelland, Maier & Neustadt, PC
1940 Duke Street
Alexandria VA 22314

In Re: Patent Term Extension
Application for
U.S. Patent No. 6,107,458

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 6,107,458, which claims the human drug product Mycamine® (micafungin sodium), a pharmaceutical composition comprising Mycamine® (micafungin sodium) and a method of using Mycamine® (micafungin sodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 996 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent Nos. 5,376,634 and 6,265,536 based on the regulatory review period of NDA No. 21-754 for the human drug product, Mycamine® (micafungin sodium).

Applicant also has sought extension under 35 U.S.C. § 156(d)(1) for U.S. Patent Nos. 5,376,634, 6,107,458 and 6,265,536 for NDA 21-506. Notices of Final Determination will be sent under separate cover for each patent for NDA 21-506. 35 U.S.C. § 156(a)(2) states that, "the term of the patent has never been extended under subsection(e)(1) of this section." Therefore, Applicant cannot extend the same patent for the approvals of NDA 21-506 and NDA 21-754. Accordingly, two patents are eligible for extension based on the regulatory review periods for Mycamine® (micafungin sodium) in NDA 21-506 and 21-754.

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the applications for patent term extension for the above-identified patent and U.S. Patent No. 6,265,536 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted. (Absent an express election, a certificate of extension will be issued in U.S. Patent No. 5,376,634.) In the absence of a request for reconsideration, and if U.S. Patent No. 6,107,458 is elected, the Commissioner will issue to the applicant a certificate of extension, under seal, for a period of 996 days in U.S. Patent No. 6,107,458.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of September 20, 2006, (71 Fed. Reg. 54994). Under 35 U.S.C. § 156(c):

Period of Extension	=	½ (Testing Phase) + Approval Phase
	=	½ (2,221 days - 878 days) + 325 days
	=	996 days (2.7 years)

Since the regulatory review period began March 29, 1998, before the patent issued (August 22, 2000), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From March 29, 1998, to and including, August 22, 2000, is 878 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,107,458
Granted:	August 22, 2000
Original Expiration Date[1]:	September 29, 2015
Applicant:	Hidenor Ohki, et al.
Owner of Record:	Fujisawa Pharmaceutical Co., Ltd.
Title:	Polypeptide Compound and a Process for Preparation Thereof
Product Trade Name:	Mycamine® (micafungin sodium)
Term Extended:	996 days
Expiration Date of Extension:	June 21, 2018

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450

By FAX: (571) 273-7755

[1]Subject to the provisions of 35 U.S.C. § 41(b).

Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE Mycamine® (micafungin sodium)
FDA Docket No.: 2006E-0345